REMARKS

Claims 1-88 are pending in the application. Claims 1, 2, 4-6, 17, 18 and 20-22 are rejected. Claims 1-7 and 17-23 are objected to. Claims 8-16 and 24-88 are withdrawn from consideration. No claims are allowed.

Claims 1 and 17 have been cancelled without prejudice or disclaimer. Applicants reserve the right to file one or more continuation, divisional and/or continuation-in-part applications directed to the canceled subject matter and/or any other subject matter disclosed in the instant specification.

Claims 2-7 and 18-23 are presented for further prosecution. Claims 2-7 and 18-23 have been amended to more clearly describe and distinctly claim the subject matter the Applicants consider their invention. Specifically, the claims have been amended to replace "cetirizine" with "[2-[4-[(4-chlorophenyl)-phenyl methyl]-1-piperazinyl] ethoxy] acetic acid." Support for the amendment can be found throughout the specification and claims as originally filed, *e.g.*, page 1, ¶ 0001, and page 22, claim 1. No new matter has been introduced by the amendments.

Reconsideration of the claim rejections and allowance of the pending claims in view of the amendments above and following remarks are respectfully requested.

Claim Rejections – 35 U.S.C. § 102

Claims 1, 6, 17 and 22 are rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Cossement et al. (GB 2225321). According to the Examiner, Cossament teaches the compound and the process for making levorotatory and dextrorotatory dihydrochloride salts of cetirizine.

Claims 1 and 17 have been cancelled, thereby rendering the rejection with respect to these claims moot, and claims 6 and 22 have been amended to depend from claims 2

and 18, respectively, which have not been rejected over Cossement. Accordingly, Applicants submit that claims 6 and 22 are not anticipated by the prior art of record, and reconsideration of this basis for rejection is respectfully requested.

Claim Rejections – 35 U.S.C. § 112

(a) Claims 6 and 22 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description and enablement requirements. According to the Examiner, there is a lack of description as to whether the compositions are able to maintain the compound in the crystalline forms claimed. Similarly, according to the Examiner, the specification lacks direction or guidance for maintaining the compound in the crystalline forms claimed. In particular, the Examiner states that polymorphs can convert from one form to another during pharmaceutical drug manufacturing. Applicants respectfully traverse this basis for rejection.

Claims 6 and 12 are directed to pharmaceutical compositions comprising a crystalline form of a dextrorotatory dihydrochloride salt of [2-[4-[(4-chlorophenyl)-phenyl methyl]-1-piperazinyl] ethoxy] acetic acid having substantially the same X-ray diffraction pattern as shown in FIG. 1 and a crystalline form of a levorotatory dihydrochloride salt of [2-[4-[(4-chlorophenyl)-phenyl methyl]-1-piperazinyl] ethoxy] acetic acid having substantially the same X-ray diffraction pattern as shown in FIG. 2, respectively. Regarding the Examiner's concern that polymorphs can convert from one form to another during pharmaceutical drug manufacturing, Applicants submit that this is mere conjecture on the Examiner's part in this case. In fact, the instant specification states on page 16, ¶ 0064, that "[t]he amorphous and crystalline forms of dihydrochloride salt of cetirizine described herein are thermally stable and may be used as an active

ingredient in pharmaceutical formulations." (Emphasis added.) The Examiner has presented nothing to question the objective truth of the statement. *See* MPEP § 2164.04.

Even if this were not the case, claims 6 and 12 contain no limitation requiring that the polymorphic forms be maintained indefinitely, or that they be the only polymorphic forms present in the compositions, and it is error for the Examiner to read such limitations into the claims. As MPEP 2164.01(b) states:

> Naturally, for unstable and transitory chemical intermediates, the "how to make" requirement does not require that the applicant teach how to make the claimed product in stable, permanent or isolatable form. *In re Breslow*, 616 F.2d 516, 521, 205 USPQ 221, 226 (CCPA 1980).

Here, the instant specification at page 16, ¶ 0064 to page 17, ¶ 70, clearly describes and enables the preparation of pharmaceutical compositions comprising the claimed polymorphic forms. Furthermore, one of ordinary skill in the art could easily ascertain whether the claimed polymorphic forms of cetirizine dihydrochloride were present in a given composition, such as by X-ray powder diffraction techniques (*see* instant specification, page 8, ¶ 0040 to page 10, ¶ 46; page 12, ¶ 0054 to page 13, ¶ 0057; page 14, ¶ 0059 to page 15, ¶ 0060), and thus determine whether a given composition fell within the scope of claims 6 and 12.

Accordingly, Appellants submit that claims 6 and 12 are not invalid for lack of written description and enablement, and reconsideration of this basis for rejection is respectfully requested.

(b) Claims 2, 4, 5, 18, 20 and 21 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. According to the Examiner, the terms "substantially"

and "about" in the claims have indefinite meanings. Applicants respectfully traverse this basis for rejection.

According to the MPEP 2173.05(b):

> The fact that claim language, including terms of degree, may not be precise, does not automatically render the claim indefinite under 35 U.S.C. 112, second paragraph. *Seattle Box Co., v. Industrial Crating & Packing, Inc.*, 731 F.2d 818, 221 USPQ 568 (Fed. Cir. 1984). Acceptability of the claim language depends on whether one of ordinary skill in the art would understand what is claimed, in light of the specification.

Contrary to the Examiner's position, Applicants submit that one skilled in the art would ascertain the scope of the claimed subject matter in light of the specification. Specifically, the instant specification's teaching at page 9, ¶ 0044 to page 10, ¶ 0045, of the possible margin of error in assignment of 2 theta angles and d-spacings clearly delineates to one skilled in the art the scope of the term "substantially" in claims 2 and 18 in conjunction with the claimed X-ray powder diffraction patterns. Similarly, the instant specification's disclosure at page 10, ¶ 0047, that the DSC and FT-IR data were obtained on particular instruments under specific conditions clearly delineates to one skilled in the art the scope of the term "about" in claims 4, 5, 20 and 21 in conjunction with the claimed DSC and IR peaks in light of known inter-instrument variability.

Accordingly, Applicants submit that claims 2, 4, 5, 18, 20 and 21 are not indefinite, and reconsideration of this basis for rejection is respectfully requested.

(c) Claims 2 and 18 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. According to the Examiner, claims 2 and 18 are indefinite because they improperly refer to Figures 1 and 2 of the specification. Applicants respectfully traverse this basis for rejection.

According to MPEP § 2173.05(s):

> Incorporation by reference to a specific figure or table "is permitted only in exceptional circumstances where there is no practical way to define the invention in words and where it is more concise to incorporate by reference than duplicating a drawing or table into the claim. Incorporation by reference is a necessity doctrine, not for applicant's convenience." *Ex parte Fressola*, 27 USPQ2d 1608, 1609 (Bd. Pat. App. & Inter. 1993) (citations omitted).

Consistent with MPEP § 2173.05(s), incorporation by reference of Figure 1 into claim 2 and Figure 2 into claim 18 is necessary because there is no practical way to describe the X-ray diffraction patterns in words and it is more concise than duplicating the patterns into the claims. Applicants also wish to note that incorporation by reference of X-ray diffraction patterns into patent claims is standard practice in the pharmaceutical compound art. *See, e.g.*, U.S. Patent Nos. 7,074,928, 7,060,712, 7,015,238, 6,998,503, 6,958,337 and 6,900,221. Accordingly, Applicants respectfully request reconsideration of this basis for rejection.

Claim Objections

Claims 1-7 and 17-23 are objected to because the claims refer to the invention by nomenclature and also by the name "cetirizine." The Examiner has suggested that the Applicants delete reference to "cetirizine" and refer to the invention by nomenclature. Claims 3, 7, 19 and 23 are also objected to because they allegedly depend from rejected base claims.

Claims 1 and 17 have been cancelled, thereby rendering the objection with respect to these claims moot. As per the Examiner's suggestion, claims 2-7 and 18-23 have been amended to replace "cetirizine" with "[2-[4-[(4-chlorophenyl)-phenyl methyl]-1-

piperazinyl] ethoxy] acetic acid." In addition, contrary to the Examiner's contention, claims 3 and 19 do not depend from a rejected base claim. Rather, they are independent claims which not been rejected. Also, claims 7 and 23 depend from claims 6 and 22, respectively, which have been amended to depend from claims 2 and 18, respectively, which, as discussed above, comply with the requirements of § 112, first and second paragraphs. Accordingly, reconsideration of this basis for objection is respectfully requested.

CONCLUSION

It is believed that claims 2-7 and 18-23 are now in condition for allowance, early notice of which would be appreciated. If any outstanding issues remain, the Examiner is invited to telephone the undersigned at the number indicated below to discuss the same. No fees are believed due at this time. If, however, any fees are due, the Commissioner is authorized to charge any such fee to our Deposit Account No. 50-3221.

Respectfully submitted,

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